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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,438	03/12/2004	Lars Tenerz	030481-0217	5250

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FOLEY AND LARDNER
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3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

DAWSON, GLENN K

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 09/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/798,438	TENERZ ET AL.	
	Examiner	Art Unit	
	Glenn K. Dawson	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,2 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Moriuchi, et al.-5217671.

Moriuchi discloses an introducer 24, a pressure transducer 30 at the proximal end and a display 32.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 and 5-7 are rejected under 35 U.S.C. 103(a) as obvious over Van Tassel, et al.-5728132 in view of Hammerslag-'124 and Moriuchi, et al.-5217671.

Van Tassel discloses an introducer 64 having a distal side port 92 communicating with a pressure sensor. Element 64 could also be the claimed core pin inside of 12' as shown in fig. 4. A proximal hemostatic seal 26 is present. However, it is not specifically disclosed that the pressure sensor is placed at the proximal end of the device, or that the sensor outputs a waveform and displays it. Hammerslag discloses the use of a proximal pressure sensor. It would have been obvious to have used proximal pressure sensing equipment as merely being an obvious design choice as nothing more than a mere rearrangement of known parts. Moriuchi discloses a pressure sensor which outputs a waveform to a display. It would have been obvious to have

used a pressure sensor with a waveform display so that the physician could see the real-time blood pressure.

Claims 1-3,5 and 7 are rejected under 35 U.S.C. 103(a) as obvious over Miyata, et al-5683347 in view of Moriuchi-'671.

Miyata discloses an introducer²⁴ having a distal port 23 in communication with a proximal pressure sensor. However, the pressure sensor having a waveform display is not disclosed. Moriuchi discloses a pressure sensor with a waveform display. It would have been obvious to have used a pressure sensor with a waveform display so that the physician could see the real-time blood pressure.

Claims 1-3 and 5-7 are rejected under 35 U.S.C. 103(a) as being obvious over Hammerslag-5843124 in view of Moriuchi-'671.

Hammerslag discloses a system including an introducer 300 having a proximal side port coupled to blood pressure sensing equipment. The introducer has a valve or seal at the proximal end and admits entry of a patch introducer for sealing an aperture in an arterial wall. See col. 2 lines 6-51; col. 6 lines 32-34; col. 18 lines 20-23; col. 19 lines 20-25; col. 25 lines 44-49; col. 26 lines 25-49; col. 27 lines 16-25. However, the pressure sensor having a waveform display is not disclosed. Moriuchi discloses a pressure sensor with a waveform display. It would have been obvious to have used a pressure sensor with a waveform display so that the physician could see the real-time blood pressure.

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being obvious over Scribner-5395353 in view of Moriuchi-'671.

Scribner discloses an introducer 40 having a lumen receiving blood whose pressure is measured by a pressure sensor at the proximal end. See col. 1 line 65-col. 2 line 7; col. 11 lines 13-22. However, the pressure sensor having a waveform display is not disclosed. Moriuchi discloses a pressure sensor with a waveform display. It would have been obvious to have used a pressure sensor with a waveform display so that the physician could see the real-time blood pressure.

Claims 1-3,5 and 6 are rejected under 35 U.S.C. 103(a) as being obvious over Li-6350274.

Li discloses an introducer 11 with a distal side port 40,60 communicating with a proximal pressure sensor 50. See col. 1 line 65-co. 2 line 6; col. 4 lines 33-53; col. 5 lines 1-21 and 50-59; col. 6 lines 6-8. However, the pressure sensor having a waveform display is not disclosed. Moriuchi discloses a pressure sensor with a waveform display. It would have been obvious to have used a pressure sensor with a waveform display so that the physician could see the real-time blood pressure.

Claims 1-3,5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards, et al.-6733515 in view of Hammerslag-'124 and Moriuchi-'671.

Edwards discloses an introducer with a lumen and a pressure sensor, preferably at the distal end to determine when the vessel is sealed signaled by a reduction in pressure at the distal end. However, the pressure sensor being at the proximal end, the

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waveform display and the hemostatic seal are not disclosed. Hammerslag discloses a sealing device having a hemostatic seal and a proximal pressure sensor. It would have been obvious to have used a proximal pressure sensor as merely being an obvious design choice as nothing more than a mere rearrangement of known parts. Moriuchi discloses a pressure sensor which outputs a waveform to a display. It would have been obvious to have used a pressure sensor with a waveform display so that the physician could see the real-time blood pressure. It would have been obvious to have used a hemostatic seal on the introducer in order to prevent the escape of blood.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 2 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6682489. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are merely broader in scope than those of the patent.

Claims 6 and 7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6682489 in view of Hammerslag-124.

The difference between the patent claims and the application claims is that of the application claims including a seal inside a lumen of the introducer and a hemostatic seal. Hammerslag discloses these elements. According to the preamble of claim 1 of the patent, the device is to detect sealing of a vessel puncture by a seal. It would therefore have been obvious to have provided a seal inside the introducer in order to seal the puncture. It also would have been obvious to have provided a hemostatic seal on the claimed introducer in order to prevent the escape of blood.

Allowable Subject Matter

Claim 4 is allowed.

Response to Arguments

Applicant's arguments filed 07-12-2005 have been fully considered but they are not persuasive.

Applicant argues that the prior art does not disclose "introducers", and uses as evidence that the catheters of the prior art do not "introduce" another device. An introducer has the "ability" to introduce something. It doesn't need to actually introduce anything to be an introducer. As long as it has a lumen, it could be used to introduce a smaller instrument therethrough. An introducer does not cease to be an introducer when the device or instrument it is introducing is removed. The prior art is capable of

introducing other flexible devices. The recitation of the path being a "blood path" is intended use. Since the blood cannot be positively recited in the claim, the "blood path" is nothing more than a "path".

Conclusion


THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K. Dawson whose telephone number is 571-272-4694. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Glenn K Dawson
Primary Examiner
Art Unit 3731

Gkd
21 September 2005